



UNIT STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office

Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

DK

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
-----------------	-------------	----------------------	---------------------

08/955,373 10/21/97 MOURITSEN

5 P58774US3

EXAMINER

HM12/0426

JACOBSON PRICE HOLMAN AND STERN
THE JENIFER BUILDING
400 SEVENTH STREET NW
WASHINGTON DC 20004-2201

SCHIADRON, R.
ART UNIT PAPER NUMBER

1644
DATE MAILED:

8

04/26/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 08/955,373	Applicant(s) Mouritsen et al.
	Examiner Ron Schwadron, Ph.D.	Group Art Unit 1644

Responsive to communication(s) filed on _____.

This action is FINAL.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 1 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

Claim(s) 26, 28-43, 45, and 46 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

Claim(s) _____ is/are allowed.

Claim(s) _____ is/are rejected.

Claim(s) _____ is/are objected to.

Claims 26, 28-43, 45, and 46 are subject to restriction or election requirement.

Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on _____ is/are objected to by the Examiner.

The proposed drawing correction, filed on _____ is approved disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All Some* None of the CERTIFIED copies of the priority documents have been

received.

received in Application No. (Series Code/Serial Number) _____.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

Notice of References Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Art Unit 1644

1. **Please Note:** In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-305-3704. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Supervisory Patent Examiner Christina Chan, at 703-308-3973. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.
2. The amendment filed 2/24/99 has necessitated the following further restriction requirement.
3. Claims 13-25,27,44 have been cancelled. Claims 26,28-43,45,46 are under consideration.

4. This application contains claims directed to the following patentably distinct species of the claimed invention.

- A) a method using a modified self-protein (claim 26)
- B) a method using a modified self-protein/cytokine fusion protein (claim 29-43)

These methods use different proteins that are structurally and functionally different (eg. one method uses a fusion protein wherein the other does not).

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, no claim is generic.

5. If applicant elects invention B above, the following species election is required.
Claim 30 is generic to a plurality of disclosed patentably distinct species comprising
 - A) a method using a GM-CSF fusion protein (claims 30,31)
 - B) a method using a IL-2 fusion protein (claims 30,32).

These methods use different fusion proteins based on different cytokines wherein the different cytokines are biochemically distinct.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this

requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

6. If applicant elects invention B in paragraph 5, the following species election is required. This application contains claims directed to the following patentably distinct species of the claimed invention.

- A) a method using modified TNF-alpha (claim 33,34,39)
- B) a method using modified TNF-beta (claim 33,35,)
- C) a method using modified gamma-interferon (claim 33,36,40)
- D) a method using modified IgE (37,41)

These methods use different proteins that are structurally and functionally different.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 29 is generic.

7. If applicant elects invention B in paragraph 5, the following species election is required. This application contains claims directed to the following patentably distinct species of the claimed invention.

- A) a method wherein the antibodies are effective to treat cachexia (claims 38-40)
- B) a method wherein the antibodies are effective to treat chronic inflammatory disease (claim 42)
- C) a method wherein the antibodies are effective to treat chronic inflammatory disease (claim 43).

These methods recite that the antibodies can be used to treat different diseases wherein the diseases are unrelated and have unique pathologies and etiologies.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 33 is generic.

8. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

9. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

10. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

11. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Dr. Ron Schwadron whose telephone number is (703) 308-4680. The examiner can normally be reached Monday through Thursday from 7:30 to 6:00. A message may be left on the examiners voice mail service. If attempts to reach the examiner by telephone are

Serial No. 08/955373

5

Art Unit 1644

unsuccessful, the Examiner's supervisor, Ms Christina Chan can be reached on (703) 308-3974. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196.



RONALD B. SCHWADRON
PRIMARY EXAMINER
GROUP 1600 (160)

Ron Schwadron, Ph.D.

Primary Examiner

Art Unit 1644

April 25, 1999



RESTRICTION ELECTION FACSIMILE TRANSMISSION

DATE:

FROM/ATTORNEY:

FIRM:

PAGES, INCLUDING COVERSHEET:

PHONE NUMBER:

TO EXAMINER:

ART UNIT:

SERIAL NUMBER:

FAX/TELECOPIER NUMBER: (703) 305-3704

**PLEASE NOTE: THIS FACSIMILE NUMBER IS TO BE USED ONLY
FOR RESPONSES TO RESTRICTIONS.**

COMMENTS: _____

IF YOU HAVE NOT RECEIVED ALL THE PAGES OF THIS TRANSMISSION, PLEASE CONTACT THE ATTORNEY AT THE
TELEPHONE NUMBER LISTED ABOVE.

IN COMPLIANCE WITH 1096 OG 30, THE FILING DATE ACCORDED EACH OFFICIAL FAX TRANSMISSION WILL BE
DETERMINED BY THE FAX MACHINE DATE STAMP FOUND ON THE LAST PAGE OF THE TRANSMISSION, UNLESS THAT
DATE IS A SATURDAY, SUNDAY, OR FEDERAL HOLIDAY WITHIN THE DISTRICT OF COLUMBIA, IN WHICH CASE THE
OFFICIAL DATE OF RECEIPT WILL BE THE NEXT BUSINESS DAY.

THE DOCUMENT(S) ACCOMPANYING THIS FACSIMILE TRANSMISSION CONTAIN(S) INFORMATION FROM THE UNITED
STATES PATENT AND TRADEMARK OFFICE WHICH IS CONFIDENTIAL AND/OR LEGALLY PRIVILEGED. THIS
INFORMATION IS FOR THE USE OF THE INDIVIDUAL OR FIRM NAMED ON THIS SHEET. IF YOU ARE NOT THE
INTENDED RECIPIENT, YOU ARE HEREBY NOTIFIED THAT ANY DISCLOSURE, COPYING, DISTRIBUTION, OR THE
TAKING OF ANY ACTION IN RELIANCE ON THE CONTENTS OF THIS INFORMATION IS STRICTLY PROHIBITED. THE
DOCUMENTS SHOULD BE RETURNED TO THE PATENT AND TRADEMARK OFFICE IMMEDIATELY. IF THIS FACSIMILE IS
RECEIVED IN ERROR, PLEASE NOTIFY THE ATTORNEY LISTED HEREON IMMEDIATELY.